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**DATE:** July 26, 2005

**TO:** Examining Attorney Mr. Eisa B. Elhilo  
Group Art Unit 1751  
United States Patent and Trademark Office

**FACSIMILE NO.** 571-273-8300

**FROM:** John E. Drach, Ph.D.  
USPTO Reg. No. 32,891

**Re:** United States Patent Application Serial No. 10/088,247  
Appellants: Keen et al.  
Filed: July 26, 2002  
For: METHOD FOR COLORING KERATIN FIBERS  
Attorney Docket No. H 03609 PCT/US

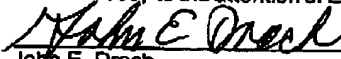
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PATENT  
Application No. 10/088,247  
Examiner: Eisa B. Elhilo  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT AND TRADEMARK  
BOARD OF APPEALS AND INTERFERENCES

Appellants: Kleen et al. Examiner: Eisa B. Elhilo  
Appl. No.: 10/088,247 Group Art Unit: 1751  
Filed: July 26, 2002  
Customer No.: 000055495  
Confirm No.: 9303  
Title: METHOD FOR COLORING KERATIN FIBERS

CERTIFICATE OF FACSIMILE TRANSMITTAL UNDER 37 C.F.R. § 1.6(d)

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**APPELLANTS' REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41**

Sir:

This reply brief is in response to the Examiner's Answer dated May 31, 2005.

**I. Rejection Of Claims 18, 20-25 and 33 Under 35 U.S.C. § 103(a)  
As Being Unpatentable Over Bernard et al. (U.S. 6,274,364)**

The Examiner continues to maintain the position that the claims 18, 20-25 and 33 are obvious over Bernard because the compositions used in the process claimed in claims 18, 20-25 and 33 are similar to the compositions taught by Bernard. For example, claim 18 recites "[a] process for coloring keratin fibers comprising

PATENT  
Application No. 10/088,247  
Examiner: Elsa B. Elhilo  
Group Art Unit: 1751  
Attorney Docket No. H 03809 PCTAUS

applying to keratin fibers (a) at least one colorant comprising at least one dye or dye precursor or combinations thereof; (b) at least one enzyme having transglutaminase activity; **and** (c) at least one active substance having substrate activity for the enzyme having transglutaminase activity." *Emphasis added.* As is evident, this claim is for a **process for coloring keratin fibers**. However, as in the rejections of record, the Examiner's Answer maintains the focus on the obviousness of the **composition** that is used in the claimed process as opposed to the claimed **process**. For example, the paragraph that bridges pages 3-4 of the Examiner's Answer stated:

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply such a **composition** to the keratin fibers by using such a method, because such a **composition** that comprises colorants, transglutaminase enzymes and substance having substrate activity of protein hydrolyze falls within the scope of those taught by Bernard et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success, because such a **composition** is expressly suggested by Bernard et al disclosure and therefore is an obvious formulation.

The Examiner has impermissibly boiled the invention down to a gist by comparing formulations, not the claimed process. See MPEP §2141.02. Appellants respectfully submit that the rejection is, therefore, improper.

However, even assuming *arguendo* that the compositions are identical, section 2142.02 of the MPEP states: "[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established."

PATENT  
Application No. 10/088,247  
Examiner: Elsa B. Elhilo  
Group Art Unit: 1751  
Attorney Docket No. H 03609 PCT/US

An objective analysis of the Bernard reference shows that it discloses, first and foremost, a newly isolated protease. The protease finds use in "promoting desquamation." *Id.*, col. 1, lines 19-20. "Desquamate" means to peel off in scales. *Merriam-Webster Dictionary Online* ([www.m-w.com](http://www.m-w.com)). Bernard further teaches that the cosmetic or pharmaceutical compositions according to the invention comprise, in a physiologically acceptable medium (vehicle, diluent or carrier), at least one polypeptide of the invention. The polypeptides of the invention are those involved in the destruction of the structures comprising the intercomeocyte junction and, therefore, in the intercomeocyte cohesion and, therefore, for promoting desquamation. (See column 1, lines 15-20 and column 5, lines 45-56). Thus, one of ordinary skill in the art would understand that Bernard's cosmetic or pharmaceutical compositions are used primarily for desquamation and that these compositions can also be applied to various areas of the skin in other types of formulations such as those taught at column 8, lines 15-24 as set forth above but within the context of promoting desquamation.

Appellants further submit that the Examiner appears to be of the view that it would be obvious to pick various components taught in the Bernard reference and employ such components so as to arrive at Appellants' claimed process. However, this is impermissible without considering context. The Bernard reference teaches that "[n]umerous pathological conditions of the skin are characterized by the production of a thick horny layer and by an abnormal desquamation, namely, by hyperkerat[osis]. The latter may occur on any anatomical skin area...". *Id.*, col. 2,

PATENT  
Application No. 10/088,247  
Examiner: Elsa B. Elhilo  
Group Art Unit: 1751  
Attorney Docket No. H 03609 PCT/US

lines 64-67; emphasis added. If abnormal skin cell build-up can occur anywhere there is skin, it is not surprising for the Bernard reference to mention **scalp care compositions** incorporating the protease described in the reference, for example shampoo, hair setting lotion, and "restructuring lotions for the hair." *Id.*, col. 8, lines 15-24, since such compositions would during use be contacted with the skin of the scalp.

The Bernard reference states that transglutaminase is a **protease activator**, and so can optionally be added to the Bernard reference's composition to activate the protease. *Id.*, col. 7, lines 17-22. Likewise, the Bernard reference teaches that certain "protein hydrolysates" are **protease activators**. *Id.*, col. 6, lines 35-43. Appellants note that the Examiner has not explained how the Bernard reference provides a motivation or suggestion for selecting substrates of transglutaminase. In fact, the **transglutaminase of the Bernard reference is present for the purpose of increasing the desquamation properties:**

Transglutaminases E and K are both **involved in the formation of the horny envelope** by bridging numerous proteins to one another, ... Accordingly, if the activity of the transglutaminases is increased either by the provision of transglutaminase activator, or by the direct provision of transglutaminase, the quantity of constituent proteins of the horny envelope is then increased, which proteins are trapped in the formation of this envelope under the influence of transglutaminase. The stratum corneum is in this case deprived of its endogenous proteins, including in particular the cystatins. The disappearance of the cystatins from the epidermis and more particularly from the stratum corneum then **has the effect of releasing the cysteine proteases whose activity is then increased, which has the effect of reducing**

PATENT  
Application No. 10/088,247  
Examiner: Elsa B. Elhilo  
Group Art Unit: 1751  
Attorney Docket No. H 03609 PCT/US

***intercorneocyte cohesion and therefore of promoting desquamation.*** ... Exemplary protease activators include glycerol, urea, EDTA, transglutaminase and reducing agents. Column 6, line 62 – col. 7, line 22; *Emphasis added.*

Since the Bernard reference encourages the above-described cascade that results when transglutaminase ties up cystatins in the epidermis (see col. 7, lines 4-16), if anything, the Bernard reference *teaches away* from Appellants' limitation of applying "at least one active substance having substrate activity for the enzyme." For example, if transglutaminase was added, and a substrate for the transglutaminase was also added, the transglutaminase would have a reduced role in desquamation. Therefore, there is no motivation to add a transglutaminase substrate, since this would interfere with the stated objective of the Bernard reference compositions (*i.e.*, to promote desquamation).

Since claims 18, 20-25 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over a single reference, the Examiner must show an art-recognized motivation to modify the reference in the manner asserted by the Office.

In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Since the Examiner's focus is on the compositions as discussed above, it has not been shown why one of ordinary skill in the art would modify the teachings of Bernard, a patent which pertains to the application of a desquamating agent to remove undesirable excess skin to arrive at claims 18, 20-25 and 33 which pertain to a process for coloring keratin fibers or for improving washing fastness of colored keratin fibers. A worker of ordinary skill in the art concerned with developing an improved process for coloring

PATENT  
Application No. 10/088,247  
Examiner: Elsa B. Elhilo  
Group Art Unit: 1751  
Attorney Docket No. H 03609 PCT/US

keratin fibers and/or for improving washing fastness of colored keratin fibers would have had no reason to look to the teachings of the Bernard reference for guidance in this endeavor let alone modify Bernard's teachings to arrive at claims 18, 20-25 and 33.

**II. Rejection Of Claims 19, 26-28 And 30-32 Under 35 U.S.C. 103(a)  
As Being Unpatentable Over Bernard et al. (U.S. 6,274,364)  
In View Of McDevitt et al. (U.S. 6,051,033)**

The Examiner continues to maintain focus on the obviousness of the **composition** that is used in the claimed process as opposed to the claimed **process** as discussed above. In addition, the Examiner attempts to make a nexus between the claims at issue and the Bernard and McDevitt references by alleging that the references are analogous art of keratin fibers formulation thereby making the teachings the references combinable to arrive at the pending claims.

Appellants contend that the references are nonanalogous art and thus, no motivation exists to combine the teachings thereof. Bernard teaches a desquamating composition and process as discussed above.

McDevitt on the other hand, is limited to a method for "treating wool, wool fibers or animal hair with a transglutaminase and a proteolytic enzyme." *Id.*, col. 1, lines 14-16. For example, the McDevitt reference states "[t]he method of the invention can be used with **wool or animal hair material in the form of top, fiber, yarn, or woven or knitted fabric**. The enzymatic treatment can also be carried out on **loose flock or on garments** made from wool or animal hair material." *Id.*, col. 4, lines 62-66; *emphasis added*. The Court of Appeals for the Federal Circuit has laid

PATENT  
Application No. 10/088,247  
Examiner: Elsa B. Elhilo  
Group Art Unit: 1751  
Attorney Docket No. H 03609 PCT/US

out two separate tests that define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986).

Application of the first test to the present case reveals that the cited references are in different fields than Appellants' invention. Bernard pertains to isolated polypeptides involved in desquamation while McDevitt to a method for treating wool and animal fibers to increase shrinkage resistance while minimizing degradation. In regard to the second test, neither reference still is reasonably pertinent to the particular problem with which the inventor is involved. It is clear from the above that the problems solved by both references are entirely different than the problem solved by Appellants' invention. Bernard solves the problem of the provision of isolated polypeptides involved in intercorneocyte cohesion and to cosmetic compositions for reducing intercorneocyte cohesion and thus for promoting desquamation. McDevitt solves the problem of treating wool and animal fibers to increase shrinkage resistance while minimizing degradation. A skilled artisan seeking guidance regarding the coloration of keratin fibers would not be motivated to consult either of these references separately or to combine their teachings having the individual references before him/her.



PATENT  
Application No. 10/088,247  
Examiner: Elsa B. Elhilo  
Group Art Unit: 1751  
Attorney Docket No. H 03609 PCT/US

III. Conclusion

For the reasons set forth above, all of the rejections of claims 18-33 should be reversed resulting in allowance of these claims.

Respectfully submitted,

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